REMARKS/ARGUMENTS

No amendments to the claims are made hereby. Claims 1 – 20 are still pending.

In the Office Action, claims 1 – 20 were rejected as being allegedly obvious over Savastano in view of Faour ('582). This rejection is respectfully traversed.

The claims as they stand do not allow for the "delay jacket" required in Savastano. It is stated in the Office Action that "...if a MOCOS core is used, the delay jacket is unnecessary...", citing column 9, lines 18 – 31. This is not a correct reading of the Savastano patent. At col. 9, lines 20 – 22, it is stated "...if a MOCOS -type core is used, *additional suspending or thickening agent in the delay jacket would be unnecessary.*" (Emphasis added.)

Indeed, Applicants find no mention in Savastano that a delay jacket is optional; on the contrary, it is at the heart of the invention disclosed. The entire patent consistently refers to the delay jacket, which allows for targeted delivery of drug to a portion of the GI tract, particularly the lower portion of the small intestine or the colon.

Therefore, Applicant' previous arguments still apply: because the primary reference does not disclose or suggest a system without said delay jacket, it fails to suggest the presently claimed invention. Moreover,

the secondary reference, Faour '582 does not make up for the shortcomings of the Savastano patent. Thus, this rejection should be reconsidered and withdrawn.

Claim 20 stands rejected over Savastano in view of Weinstein. This rejection is also traversed.

As mentioned above, Savastano does not teach what the Office Action has asserted. Weinstein does not overcome the deficiencies of Savastano. Accordingly, this rejection should be withdrawn.

Claims 1 - 5, 7 - 16, 18 and 19 were again rejected over Faour et al. (6,491,949), alone.

In response to Applicants' previous arguments, the examiner states that Faour "clearly teaches manipulating the release rate of the active agent by the addition or absence of a membrane or coat on the second or first osmotic device." (Page 7, from 5th line from the bottom to the 3rd line from the bottom.) This assertion is simply incorrect.

The passage the Examiner refers to (see page 6 of the Office Action) is column 5, lines 18 - 35. But here it does not make the statement in the manner suggested. Rather, this passage refers to the presence or absence of *additional* membranes - not whether there can be no membrane at all.

As the Office Action admits, Faour does not teach the limitation of "directly adjacent to the core portion", or greater concentration of drug on the outer layer as compared to the inner layer. The assertion in this rejection that motivation to not have a membrane between the two concentration layers lays in Faour's statement that release rate can be manipulated by the presence or absence of membranes is based on a flawed interpretation of the Faour patent.

For all the reasons given above and in previous responses, this rejection should be withdrawn.

Claims 6, 17 and 20 were again rejected as being obvious ove Faour ('949) in view of Hamel.

Again, the deficiencies of Faour are as stated above. Hamel does not make up for the shortcomings noted. Thus, there is no *prima facie* case of obviousness here either. Accordingly, this rejection should be withdrawn.

Finally, claims 1 and 3 – 5 are newly rejected over Faour ('359). This rejection is traversed.

It is respectfully submitted that the teachings of the patent have been misinterpreted or exaggerated, and really are not applicable to the present invention.

In this rejection, it is suggested that Faour '359 teaches a bilayer core ("Formulation G"), which can be coated with a semipermeable membrane to form an osmotic device. The examiner also suggests Faour discloses that "two tablet formulations (can be)...combined and coated with ...a semipermeable membrane for an osmotic device." This is simply inaccurate.

Faour '359 discloses a multi-tablet dosage system to achieve certain plasma profiles. In essence, the system requires an immediate or short acting tablet and an extended release tablet, which can be taken concurrently or sequentially (see paragraph bridging cols. 7 and 8). It is also described in that paragraph how the "unit dose" has a first tablet and a second tablet, each with a different release profile, and that these unit doses can be *packaged* (e.g. in a kit: see col. 16, line 25) separately or together.

Column 7, lines 49 – 52, contains the only disclosure that the tablets can comprise a single dosage form, where it states: "...the first and second tablets...may be ...encased in a capsule..." Such an embodiment has nothing to do with the present invention.

Nowhere does Faour disclose or suggest that the two tablets can be combined into an osmotic dosage form. Rather, the disclosure in Faour about osmotic dosage forms relates to one of the tablets being

controlled release, and how this controlled release can be an osmotic type of tablet.

The examiner notes Formulation G; this tablet is a "short acting controlled release" tablet that includes a rapid release external coat. The external coat is an enteric coating containing a relatively small amount of drug, and allows for an initial burst or release of drug. This formulation is not an osmotic dosage form, and there is absolutely no suggestion to make this an osmotic dosage form. In fact, the Faour patent only teaches well-known characteristics of osmotic tablets in describing how the extended release tablet in his system can be of an osmotic nature. There is nothing new in this regard.

The Office Action admits at page 10 that Faour does not disclose an osmotic device where an outer layer contains a higher concentration of drug than the inner layer. *This is the instantly claimed invention.* And, the invention is not simply a matter of manipulating concentrations, as suggested by the examiner.

This rejection, in effect, not only attempts to establish obviousness through hindsight reconstruction, but there simply is not even enough disclosure in Faour to support such a presumption.

Therefore, this rejection should be reconsidered and withdrawn.

This application has three Office Actions on the merits, and a personal interview has been conducted. It is respectfully submitted that the rejections have previously been adequately addressed, and it is hoped that the present response puts to rest the allegations of obviousness. None of the rejections is considered to support a *prima facie* case of obviousness. Therefore, it is respectfully requested that the Patent Office expeditiously pass this application to allowance.

If there are any matters remaining that could best be resolved by telephone, the examiner is invited to contact the undersigned at the number listed below.

This paper is being filed with a Petition for Two Month Extension of Time. If any other fees are due in this application, they may be charged to our Account No. 50-2715.

Respectfully submitted,

SHIRE LABORATORIES INC.
1550 East Gude Drive
Rockville, MD 20850
Tel: 301/838-2658
Fax: 301/838-2501
Email: elane@shirelabs.com

M. Elisa Lane
Registration No. 34,409
Attorney for Applicants